

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC. and GILEAD SCIENCES IRELAND UC, :
v. : Case No. _____
Plaintiffs, :
SAFE CHAIN SOLUTIONS, LLC; PATRICK BOYD; CHARLES BOYD; WORLDWIDE PHARMA SALES GROUP, INC. d/b/a PHARMASALES.COM.; ADAM S. BROSIUS; BOULEVARD 9229 LLC; and ISHBAY SHUKUROV, :
Defendants.

COMPLAINT

Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC (together, “Gilead” or “Plaintiffs”), by and through their counsel, Patterson Belknap Webb & Tyler LLP, for their complaint against Defendants Safe Chain Solutions, LLC (“Safe Chain”), Patrick Boyd, Charles Boyd, Worldwide Pharma Sales Group, Inc. d/b/a Pharmasales.com (“Worldwide Pharma”), Adam S. Brosius (“Brosius”), Boulevard 9229 LLC (“Boulevard”), and Ishbay Shukurov (“Shukurov”) (collectively, “Defendants”) allege as follows:

SUMMARY OF THE ACTION

1. In this action, Gilead seeks to put an immediate and permanent stop to Defendants’ knowing and willful sale, marketing, and distribution of counterfeit prescription drugs. The counterfeits are of Gilead HIV medications: life-saving treatments for patients living with HIV, and pre-exposure prophylactic medication that protects high-risk patients from HIV-1 infection when taken as prescribed. Defendants sold authentic-looking bottles of Gilead

medication to distributors and pharmacies throughout the United States, including in New York City, who in turn dispensed them to patients. But the tablets inside those bottles were not Gilead's HIV medication. They were completely different drugs. Most commonly, the counterfeits were filled with high-dose tablets of a prescription antipsychotic with debilitating side effects.

2. The counterfeitors use authentic Gilead bottles that at one point contained authentic Gilead HIV medications. The tamper-evident seals of these authentic bottles had been broken and their contents emptied. The counterfeitors inserted the foreign tablets into these empty bottles, and then re-sealed the bottles. The counterfeits were thus engineered to resemble a new, unopened, and authentic bottle of authentic Gilead HIV medication. Because federal law requires that all prescription drugs be accompanied by a "pedigree" – a document tracking every sale of the bottle from seller to seller, all the way back to the manufacturer – Defendants distributed the counterfeits with falsified documentation fraudulently purporting to trace the counterfeits to an authentic source.

3. The danger these counterfeits pose to patients is dire. The patients who receive the counterfeits unwittingly miss their HIV treatment or falsely believe themselves to be protected against HIV infection. The foreign drugs in the counterfeit bottles were never prescribed by those patients' doctors and could cause serious harm or death, through contraindicated drug-drug interactions or the onset of unanticipated side effects such as loss of consciousness while operating heavy machinery or driving.

4. Defendants willfully trafficked these dangerous counterfeits and committed fraud to cover it up. Defendant Boulevard is one of Safe Chain's several counterfeit suppliers; it both knowingly sold counterfeit HIV medications to Safe Chan and created fake

pedigrees to go with them. Safe Chain knew Boulevard was using fake pedigrees because Gilead told it so, but Safe Chain kept buying counterfeits from Boulevard anyway. In fact, for at least six months *after* receiving pharmacy and patient complaints about counterfeit HIV medications it had sold, Safe Chain continued buying thousands of bottles of Gilead medication from the *same* suppliers who sold it those counterfeits.

5. When Gilead opened an investigation after the earliest counterfeit incident and contacted Safe Chain, Safe Chain for months refused to identify the suppliers who sold it the counterfeit. When additional counterfeit reports came in and forced Safe Chain to identify its suppliers, Safe Chain moved from stonewalling to outright fraud. Safe Chain created fake pedigrees that fraudulently claimed to trace the counterfeits back to a Gilead authorized distributor, and sent those new fake pedigrees to Gilead.

6. As Gilead’s investigation intensified, Safe Chain promised Gilead that it had stopped all purchases from its previous counterfeit suppliers (*i.e.*, the ones Gilead already knew about), and said it was now purchasing from a new supplier who only purchased directly from a Gilead authorized distributor. Safe Chain also represented that it had directly confirmed, with the authorized distributor, that its supplier was in fact buying from that authorized distributor. But Safe Chain said it would only identify this new mystery supplier if, among several other conditions, Gilead first “announced” that Safe Chain had never faked a pedigree, and then released all legal claims Gilead had against Safe Chain.

7. Safe Chain’s claims about its “new” supplier were all lies. Gilead learned the identity of that new supplier through its independent investigation. This investigation revealed that the supplier was another one of Safe Chain’s typical fly-by-night counterfeiters that never registered as a distributor with the FDA and did not have licensure to sell drugs to Safe

Chain. That supplier was not buying from a Gilead authorized distributor, and its pedigrees that claimed to trace back to an authorized distributor were fake. Furthermore, Safe Chain never contacted that authorized distributor to verify its supplier's purchases, as Safe Chain falsely told Gilead it had done. The authorized distributor has had no contact with Safe Chain and it has never sold anything to Safe Chain's supplier. Once again, Safe Chain was flagrantly lying to throw off Gilead's investigation and cover up the fact that it was continuing to traffic dangerous counterfeit HIV medications.

8. Worldwide Pharma worked directly with Safe Chain to source, advertise, and sell the counterfeit Gilead HIV medications to pharmacies. Worldwide Pharma is owned and managed by Defendant Adam S. Brosius, who is under indictment for healthcare fraud, conspiracy, and violations of the anti-kickback statute. Safe Chain and Worldwide Pharma conspired to obtain Gilead HIV medications from illegitimate sources, including by setting up a deceptive "pass-through" scheme to hide the identities of unlicensed suppliers, and to market counterfeit products to pharmacies where they were dispensed to unsuspecting patients.

9. In this action, Gilead seeks injunctive relief, including a seizure at certain Defendants' premises, in order to put an immediate stop to the sale of these dangerous counterfeit medications. Gilead also seeks other injunctive and monetary relief against all Defendants for trademark infringement in violation of Section 32 of the Lanham Act (15 U.S.C. § 1114); false descriptions and false designations of origin in commerce in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125); trademark dilution in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125) and New York General Business Law § 360-1; deceptive business practices in violation of New York General Business Law § 349; and common-law unjust enrichment and unfair competition.

THE PARTIES

10. Plaintiff Gilead Sciences, Inc. is a public corporation organized under the laws of the State of Delaware, with more than 12,000 employees. Its principal place of business is 333 Lakeside Drive, Foster City, California 94404. Gilead develops and markets a large portfolio of lifesaving medications, including drugs for the treatment or prevention of HIV. Gilead is the registered owner of certain well-established and famous registered trademarks that appear on the packaging, tablets, and package inserts of certain genuine HIV medications.

11. Plaintiff Gilead Sciences Ireland UC (“Gilead Ireland”) is a private unlimited company organized under the laws of Ireland, with its principal place of business at IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland. Gilead Sciences, Inc. is the ultimate parent of Gilead Ireland. Gilead Ireland is the registered owner of certain well-established and famous registered trademarks that appear on the packaging, tablets, and instructional inserts of certain genuine HIV medications.

12. Gilead Sciences, Inc. and Gilead Ireland (together, “Gilead”) are the collective owners of a number of well-established and famous registered trademarks (the “Gilead Marks”) that appear on genuine HIV medications. A complete list of these trademarks is depicted at Exhibit A hereto. Gilead also owns and uses distinctive packaging (the “Gilead Trade Dress”) to distinguish its HIV products in the marketplace, which is depicted at Exhibit B hereto.

13. Defendant Safe Chain Solutions, LLC (“Safe Chain”) is a Delaware limited liability corporation with a principal place of business in Cambridge, Maryland.

14. Defendant Patrick Boyd is an individual residing in Maryland. Together with his brother Charles, Patrick Boyd is a founder, owner, and managing principal of Safe

Chain. Patrick Boyd managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV medications. Patrick Boyd directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.

15. Defendant Charles Boyd is an individual residing in Maryland. Together with his brother Patrick, Charles Boyd is a founder, owner, and managing principal of Safe Chain. Charles Boyd serves as CEO of Safe Chain. Charles Boyd managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV medications. Charles Boyd directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.

16. Defendant Worldwide Pharma Sales Group, Inc. d/b/a Pharmasales.com (“Worldwide Pharma”) is a Delaware corporation with a principal place of business in Delray Beach, Florida.

17. Defendant Adam S. Brosius (“Brosius”) is an individual residing in the United States. Brosius is the founder, owner, and principal of Worldwide Pharma. Brosius managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV medications.

18. Defendant Boulevard 9229 LLC (“Boulevard”) is a New York limited liability corporation with a principal place of business in Rego Park, Queens, New York.

19. Defendant Ishbay Shukurov (“Shukurov”) is an individual residing in Brooklyn, New York. Shukurov is the owner and sole proprietor of Boulevard. Shukurov managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV medications.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 1121(a), 1331, 1338, and 1367 and general principles of ancillary and pendent jurisdiction.

21. The Court has personal jurisdiction over each of the Defendants because each of the Defendants has sufficient minimum contacts with New York and with this District so as to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice. Among other things, Safe Chain and Worldwide Pharma sold, and conspired together to sell, counterfeits to pharmacies in New York City. Moreover, Defendant Boulevard is located in Queens, and Defendant Shukurov resides in Brooklyn. Boulevard and Shukurov sold counterfeits to Safe Chain in this District, and Safe Chain purchased counterfeits from Boulevard and Shukurov in this District.

22. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(b) because Boulevard's offices are located in this District, because Shukurov lives in this District, because Safe Chain and Worldwide Pharma conspired with Boulevard and Shukurov to purchase and ship counterfeits from this District, and because a substantial part of the events giving rise to Gilead's claims occurred in this District.

FACTUAL ALLEGATIONS

A. Gilead's HIV Medications

23. For more than three decades, Gilead has strived to create a healthier world for all by delivering innovative therapeutics that aim to prevent, treat, or cure life-threatening diseases. Gilead relentlessly pursues advancements in science with the goal of bringing to patients around the world treatments that improve care in areas of unmet medical needs.

24. Gilead has transformed care for people living with HIV and hepatitis C, developing pioneering medicines including the world's first single tablet regimen to treat HIV, the first prophylactic medicine to prevent HIV infection, and four hepatitis C therapies.

25. BIKTARVY® is a complete, one-pill, once-a-day prescription medication used to treat HIV. Developed by Gilead and first approved by the FDA in 2018, BIKTARVY® is a single-tablet drug combination medicine for the treatment of HIV-1 infection, combining the unboosted integrase strand transfer inhibitor (INSTI) bictegravir with Gilead's dual nucleoside reverse transcriptase inhibitor (NRTI) backbone of emtricitabine and tenofovir alafenamide, the components of Gilead's DESCovy®.

26. BIKTARVY® has a demonstrated long-term efficacy and safety profile, has few drug interactions and side effects, and a high barrier to developing drug resistance.

27. Although BIKTARVY® does not cure HIV, when taken every day as prescribed, it can lower the amount of virus in a patient's blood to undetectable levels. In addition to halting the progression of HIV, research shows that having undetectable levels of the virus prevents transmission of HIV through sex, protecting a patient's sexual partners from possible transmission.

28. BIKTARVY® can also help increase the number of a patient's CD4 T-cells, which are an important part of a person's immune system. HIV attacks and destroys CD4 T-cells, which decreases a patient's ability to fight off other infections and increases the risk of a patient contracting an opportunistic infection, which could lead to serious illness or death.

29. One of the most significant developments in the fight against HIV is the development of drugs known as pre-exposure prophylaxis, or PrEP: a method of HIV prevention

whereby individuals who are HIV-negative but at-risk for HIV infection proactively take medication on an ongoing basis to decrease their risk of acquiring HIV.

30. DESCovy® is a therapy developed and manufactured by Gilead that can be taken for PrEP. The drug comes in the form of a tablet. The FDA-recommended dosage is one tablet per day.

31. When taken as indicated, DESCovy® is highly effective at preventing HIV-1 infection in individuals exposed to the virus.

32. DESCovy® was approved by the FDA for PrEP in 2019. It has been instrumental in preventing the spread of HIV in areas in the United States where there is a high prevalence of HIV.

33. Gilead has used and is currently using the Gilead Marks and the Gilead Trade Dress in commerce in connection with its sale of HIV medications, and plans to continue such use in the future. Gilead prominently displays the Gilead Marks in its advertising and promotional materials.

34. Gilead has engaged and continues to engage in activities designed to promote its HIV medications and the business and goodwill associated with its trademarks, and to expand the use and reputation of its trademarks, trade dress, logos, copyrights, and property throughout the United States. All of these trademarks and trade dress symbolize business goodwill of Gilead and are invaluable assets to Gilead.

B. Defendants' Counterfeit HIV Medications

35. Gilead learned of Defendants' counterfeiting operation through a series of patient and pharmacy complaints that were reported to Gilead. In the past several months, Gilead has received multiple complaints from patients and pharmacies about bottles of Gilead

HIV medications that were sold by Safe Chain and that, when opened, were actually filled with an entirely different drug.

36. Gilead was not able in all instances to recover the counterfeit bottles of HIV medications that were the subject of these patient or pharmacy complaints. But Gilead has to date been able to acquire several bottles of counterfeit HIV medications that Safe Chain sold to U.S. pharmacies. Gilead's in-house experts examined the bottles and their contents and determined the products to be counterfeit. Gilead also sent the bottles to an outside laboratory who performed analyses of the bottles, the tamper-proof seals and the adhesives used to affix them, and the tablets inside the bottles. The outside lab also confirmed that the HIV medications sold by Safe Chain were counterfeit.

37. Authentic Gilead HIV medication is FDA approved for sale only in Gilead's original, sealed manufacturer bottles: it cannot be sold or dispensed in generic pharmacy vials. The lip of each authentic bottle is covered with a foil tamper-evident seal, which is covered by a screw-on lid. Safe Chain's counterfeits appeared to use authentic Gilead bottles that once contained authentic Gilead medication. The original foil on the bottles had been stripped away, the authentic medication removed and replaced with foreign medication, and then a replica of the tamper-evident seal was used to re-seal the bottle. Traces of the original tamper-proof seal remained in the grooves of the counterfeit bottles and were visually distinguishable from the replica seal. Lab testing confirmed that both the replica seal and the adhesive used to affix it did not match the original, authentic foil and adhesive used on authentic Gilead product.

38. The outside laboratory's testing also confirmed what was apparent to the medical professionals and in-house experts who examined the counterfeits: that the tablets inside the bottle were not the Gilead medication listed on the bottle. In one instance, the counterfeit

bottle contained a generic over-the-counter analgesic. But the most common contents of the tested counterfeits was quetiapine furmarate, a non-Gilead medication that is marketed under the brand name SEROQUEL XR® and is also available as a generic.

39. Quetiapine is a prescription anti-psychotic medication with a number of known serious side effects. Quetiapine very commonly causes a strong sedated state or drowsiness. As noted on the FDA labelling for the drug, these effects are especially acute for first-time users of the drugs. One patient who unknowingly took SEROQUEL XR® after receiving a counterfeit bottle of BIKTARVY® reported that the patient could not speak or walk afterwards. Patients who are prescribed quetiapine are warned against driving or operating machinery.

40. Quetiapine also poses serious dangers to patients with common health conditions, such as high blood pressure, diabetes, and low white blood counts, whose conditions must be closely monitored while taking quetiapine.

41. Because of its potency, the FDA-approved dosage recommends starting labelling for quetiapine recommends that some new patients be given a small dose – 50 milligrams a day for many conditions – that can be increased over time as the patient’s physician tracks the side effects and monitors the patients’ reaction to the drug. The counterfeit Gilead HIV medication contained 300-milligram tablets of quetiapine.

42. Of course, patients who ingest quetiapine from a counterfeit bottle of HIV medication have no idea that they are taking a medication with these side effects and receive no warning of the possible consequences of doing so. They have no idea they are not supposed to drive, operate heavy machinery, or engage in other activities where sedation or drowsiness are dangerous, and as a result are placed in grave danger of injury or death.

43. Patients who receive the Defendants' counterfeits do not receive their prescribed HIV medications. For patients treating HIV infection, it is very important that the patient take the Gilead medication once a day, every day. If a patient skips doses for even a short period of time, the patient faces the risk that the patient's viral load – that is, the amount of HIV in their blood – will increase. Viral rebound can have severe consequences. Over time, it can weaken the patient's immune system and increase the possibility of infections; it can result in progression of the disease and lead to the development of AIDS; and it can make patients more likely to infect their sexual partners.

44. Patients taking DESCovy for PrEP® must also take the medication regularly to receive the prophylactic benefits of the drug. DESCovy for PrEP® is recommended only for individuals at a risk for HIV infection. A patient who unknowingly discontinues their DESCovy® treatment because they have received counterfeit medication puts themselves at high risk for contracting HIV while still believing they are being protected from infection.

C. Defendants' Counterfeit Pedigrees

45. Under the Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. §§ 360eee *et seq.*, every sale or transfer of a prescription drug must be accompanied with a record showing the chain of all sales or transfers of that drug, going back to the manufacturer. In the industry, this is known as the drug's "pedigree," and is also referred to as the drug's DSCSA documentation or "T3" documentation – standing for the three "Ts" of transaction information, transaction history, and transaction statement that must be included with the pedigree.

46. The FDA’s website states that the purpose of the DSCSA’s tracing requirements is to “enhance FDA’s ability to help protect consumers from exposure to drugs that may be counterfeit.”

47. Counterfeit bottles of HIV medications cannot have valid pedigrees. In order to sell their counterfeit HIV medications, the Defendants created and utilized fake pedigrees that fraudulently represented that the drug could be traced back to an authentic sale from Gilead.

48. Gilead obtained the purported pedigrees for several counterfeit bottles of Gilead HIV medications sold by Safe Chain. Those pedigrees were also fake, many of them obviously so.

49. In the United States, the only distributors to which Gilead sells its HIV medications are Gilead authorized distributors. This is a well-known fact in the industry, and consistent with the practices of other major pharmaceutical manufacturers. Gilead has sixteen U.S. authorized distributors for HIV medications, and their names are publicly posted on Gilead’s website. Safe Chain has expressly acknowledged that it is aware that Gilead sells HIV medications only through those Gilead authorized distributors.

50. Many of the pedigrees for the counterfeits contained an immediately detectable falsehood: that Gilead had initially sold the medication to a distributor other than an authorized distributor. Other pedigrees for the counterfeits did list an authorized distributor as the first purchaser of the drug, and then claimed the drug was sold from there to one or more distributors before it was purchased by Safe Chain. Gilead was able to confirm from its internal records that it had not sold the specific lots of the medication to the authorized distributor listed

on the pedigree. Gilead also confirmed with the authorized distributors that the pedigrees were false.

51. While Gilead has only been able to recover a sample of the counterfeits that have been reported to it, as part of its investigation Gilead has received copies of pedigrees for thousands of bottles of Gilead HIV medications trafficked by the Defendants in this action. Those pedigrees are fake: they fraudulently list an initial sale made by Gilead that did not occur. Every one of those bottles is an illegitimate product and pursuant to the DSCSA must be quarantined and cannot lawfully be sold.

52. Every authentic bottle of HIV medications that Gilead sells comes with a pedigree that accurately discloses when and to whom Gilead sold that bottle. The pedigree is part of the product that Gilead sells. For Gilead, the pedigrees are anti-counterfeiting measures and also play other important internal quality-control functions. For the distributors, pharmacies, and patients that buy Gilead's HIV medications, authentic pedigrees that accurately disclose the original sale of the product are an important feature of Gilead's products that guarantee the medication's authenticity and safety. Bottles of Gilead medication that have fake or altered pedigrees, such as those that do not list Gilead's original, authentic sale of the medication, are materially different from authentic Gilead product as Gilead sells it in U.S. commerce.

D. Safe Chain's Willful Sale of Counterfeit HIV Medications After Being Repeatedly Informed It Was Selling Counterfeits

53. Safe Chain holds itself out to be a legitimate pharmaceutical distributor, specializing in HIV medications among a few other areas. In reality, Safe Chain is a willful trafficker of counterfeit HIV medications, and has knowingly put an untold number of patients' health and lives at risk in order to make an illicit profit.

54. Over the past several months, Gilead received report after report of counterfeit Gilead HIV medications from pharmacies and customers, all of which Safe Chain had sold to the dispensing pharmacy. Gilead initially treated Safe Chain as an unwitting distributor of counterfeits, and attempted to work cooperatively with the company to address the problem. Legitimate distributors who learn they have sold counterfeits – let alone bottles of counterfeit HIV medications that actually contain a high-dose antipsychotic – will do everything they can to ensure they do not sell any more counterfeits, and assist the manufacturer in tracking down the source of the counterfeits. Safe Chain did the opposite.

55. In response to Gilead’s communications, Safe Chain engaged in a campaign of delay and obfuscation, hiding its suppliers and refusing to provide Gilead with crucial information about the counterfeits. Meanwhile, Safe Chain continued to buy thousands of bottles of Gilead medication, all of them with fake pedigrees, from the same counterfeit suppliers, even after Safe Chain had been informed that these suppliers were selling counterfeit Gilead HIV medications.

1. Safe Chain Is Notified It Is Selling Counterfeits but Obstructs Gilead’s Investigation and Continues Purchasing from Its Counterfeit Supplier

56. In August 2020, White Cross Pharmacy, located in California, reported to Gilead and Safe Chain that a patient had returned a bottle of BIKTARVY® that had foreign medication inside. The pharmacy had purchased that counterfeit from Safe Chain. Knowing that the pharmacy had already reported the counterfeit to Gilead, Safe Chain’s co-founder Charles Boyd wrote to Gilead to disclose White Cross Pharmacy’s report. On September 11, 2020, Gilead asked Safe Chain to identify who had supplied this counterfeit to Safe Chain, but Safe Chain refused to do so.

57. In November 2020, Gilead again asked Safe Chain to provide the pedigree and identify the supplier from whom Safe Chain had purchased the counterfeit. Safe Chain refused, stating only that it had purchased the counterfeits from an “authorized trading partner.” Gilead responded that was “wholly inadequate,” noting that Gilead needed that information “to determine how this illegitimate product made its way into the supply chain.”

58. Between August 2020 and early February 2021, Gilead asked Safe Chain on at least five different occasions to produce the pedigree for the counterfeit it sold to White Cross Pharmacy, but each time Safe Chain either refused or ignored the request.

59. In October 2020, Safe Chain received another report of counterfeit BIKTARVY® from a different pharmacy – The Medicine Shoppe in Maryland. The counterfeit BIKTARVY® bottle was actually filled with 300 mg tablets of SEROQUEL XR®. But this time, Safe Chain knew that the pharmacy had not immediately reported the counterfeit to Gilead. Hoping to avoid detection, Safe Chain tried to dissuade the pharmacy from reporting the incident. In an email to The Medicine Shoppe, Safe Chain’s Director of Compliance suggested that instead of “contact[ing] Gilead,” the pharmacy should “return[] it to us, and then let us send it back.” Safe Chain never did report this counterfeit to Gilead.

60. Gilead only learned about this October 2020 counterfeit report because in February 2021, The Medicine Shoppe received from a patient *another* report of counterfeit BIKTARVY® that the pharmacy had purchased from Safe Chain. Gilead promptly interviewed The Medicine Shoppe. During that interview, the pharmacy disclosed its October 2020 counterfeit report to Safe Chain, stating that it had returned the counterfeit bottle to Safe Chain but heard nothing back.

61. When Gilead confronted Safe Chain about the October 2020 counterfeit report from The Medicine Shoppe, Safe Chain claimed it *had* reported that incident to Gilead, and that Gilead was at fault for not responding to Safe Chain's report. That claim was false. Gilead immediately demanded, and later repeated its demand, that Safe Chain substantiate its claim that it had reported the October 2020 incident. Safe Chain never provided any such corroboration, because it never made any such report to Gilead.

62. Each of the three known examples of counterfeit BIKTARVY® that were reported to Safe Chain between August 2020 and early February 2021 had been supplied to Safe Chain by Gentek LLC ("Gentek"), located in Stamford, Connecticut. During that period, Safe Chain worked to conceal the counterfeit reports from Gilead, and when Gilead learned about them, refused to provide pedigrees or identify its counterfeit supplier. During that same time period – from the time Safe Chain was first directly told that the Gilead medication it sourced from Gentek was counterfeit to the time Safe Chain revealed Gentek's identity to Gilead – **Safe Chain purchased over 8,000 bottles of Gilead HIV medications from Gentek for over \$20 million, including over 3,000 bottles of BIKTARVY®, all while knowing that Gentek was selling dangerous counterfeits.**

2. Safe Chain Provides Fake Pedigrees to Gilead

63. Realizing that Gilead's counterfeit investigation was escalating and that it would not be possible to stonewall and obstruct the investigation indefinitely, on February 22, 2021, Safe Chain finally provided the pedigree for the counterfeit BIKTARVY® that White Cross Pharmacy had reported *six months* prior. Safe Chain also provided pedigrees – one from Safe Chain and one from its supplier – for the two counterfeit bottles of BIKTARVY® that were reported by The Medicine Shoppe. Each of the pedigrees indicated that Safe Chain had

purchased the counterfeit from Gentek. Each pedigree also indicated that Gentek had purchased the counterfeit from Drogueria Betances, a Gilead authorized distributor located in Puerto Rico.

64. Gilead determined that those pedigrees were fake. Gilead did not sell the lot numbers listed on the pedigrees to Drogueria Betances. And Gilead confirmed with Drogueria Betances that Gentek was not one of its customers.

65. Gilead has recently learned that Safe Chain not only provided Gilead with fake pedigrees, but that Safe Chain altered those pedigrees by adding false information immediately before sending them to Gilead.

66. Gilead recently obtained from Safe Chain's customer, The Medicine Shoppe, the pedigree that Safe Chain sent to the Medicine Shoppe in the normal course of business – i.e., at the time it sold the counterfeit bottle to the pharmacy. The pedigree that Safe Chain sent to its customer and the pedigree it sent to Gilead should, of course, be identical. They are not, as shown in the figure below:

Pedigree that Safe Chain sent to pharmacy

SAFE CHAIN SOLUTIONS, LLC
Drug Supply Chain Security Act Document Doc# 00000019202

(T) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01	Reference Number: 01140811 Document Type: Invoice Reference Date: 01/08/21
Lot Number: 6400505A Quantity: 3 Unique Serial #: CDGXBA	
Lot Number: 6400505A Quantity: 1 Unique Serial #: CCZCFA	

(TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES
Manufacturer's Information:

SOLD TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref:	SHIPPED TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref:
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref: 01/07/21 PO#01211389	SHIPPED TO: Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref: 01/08/21 RC#016349
SOLD TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref: 01/08/21 01S36758001	SHIPPED TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref: 01/08/21 01S36758001
SOLD TO: Name: Address: Date Purchased & Ref:	SHIPPED TO: Name: Address: Date Received & Ref:
SOLD TO: Name: Address: Date Purchased & Ref:	SHIPPED TO: Name: Address: Date Received & Ref:

Pedigree that Safe Chain sent to Gilead

SAFE CHAIN SOLUTIONS, LLC
Drug Supply Chain Security Act Document Doc# 00000019202

(T) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01	Reference Number: 01140811 Document Type: Invoice Reference Date: 01/08/21
Lot Number: 6400505A Quantity: 3 Unique Serial #: CDGXBA	
Lot Number: 6400505A Quantity: 1 Unique Serial #: CCZCFA	

(TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES, INC
Manufacturer's Information: 1800 WHEELER AVENUE LA VERNE CA 91750

SOLD TO: Name: DROGUERIA BETANCES Address: LUIS MUÑOZ MARIN AVE CAGUAS PR 00725 Date Purchased & Ref: 10/05/20 85160	SHIPPED TO: Name: DROGUERIA BETANCES Address: LUIS MUÑOZ MARIN AVE CAGUAS PR 00725 Date Received & Ref: 10/05/20 85160
SOLD TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref: 10/06/20 2719	SHIPPED TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref: 10/06/20 2719
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref: 01/07/21 PO#01211389	SHIPPED TO: Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref: 01/08/21 RC#016349
SOLD TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref: 01/08/21 01S36758001	SHIPPED TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref: 01/08/21 01S36758001
SOLD TO: Name: Address: Date Purchased & Ref:	SHIPPED TO: Name: Address: Date Received & Ref:

67. The pedigree that Safe Chain originally sent to The Medicine Shoppe listed an initial sale directly from Gilead to Gentek – an obvious red flag, because Gentek is not a Gilead authorized distributor. That original pedigree also failed to fill in basic details, such as Gilead’s address and the date and reference number for the supposed initial sale from Gilead to Gentek.

68. But the pedigree that Safe Chain later sent to Gilead had an additional transaction added to the sales chain: a purported initial sale from Gilead to Drogueria Betances, the Gilead authorized distributor. Moreover, the information missing on the original pedigrees – Gilead’s address, date of initial sale, and reference number for initial sale – are now filled in (fraudulently, because those initial sales never happened). In other words, the original pedigrees, which were immediately recognizable as fake, had been altered to include information that was also fake, but was harder to recognize as such.

69. Safe Chain sent both sets of pedigrees as PDF files that contain metadata showing the date they were created. Safe Chain created the pedigree it sent to The Medicine Shoppe on January 8, 2021, the day it sold the bottles to the pharmacy, as would be expected. But Safe Chain created the altered pedigree on February 19, 2021 – meaning the altered pedigree was created outside the normal course of business, and just days before Safe Chain sent it to Gilead.

3. Safe Chain’s Willful Purchases of Counterfeits from Defendant Boulevard

70. On October 5, 2020, Safe Chain contacted Gilead with a cryptic request to verify the expiration date on a bottle of BIKTARVY®. Gilead responded by asking Safe Chain why it was inquiring about the product and requesting more information and photographs of the bottle. Safe Chain did not provide photographs or otherwise explain what had prompted the

inquiry, but it did send a purported pedigree document for the bottle. The pedigree in question claimed an initial sale of BIKTARVY® from Gilead to a “drug co-op,” and then to Defendant Boulevard, and then to Safe Chain. Gilead responded on October 9, 2020 that the transaction history was incorrect, and that the drugs on the pedigree “should be treated as an illegitimate product and quarantined and should be reported to the FDA.” Safe Chain did not respond to Gilead’s e-mail.

71. In March 2021, Gilead received two new complaints from pharmacies – one in New York City and the other in Washington D.C. – about counterfeit bottles of BIKTARVY® and DESCovy® that the pharmacies had purchased from Safe Chain. The pharmacy in Washington D.C. provided the pedigree for the counterfeit bottle of DESCovy®, which indicated that Safe Chain had purchased it from Defendant Boulevard. Gilead and its outside lab tested both bottles and confirmed they were counterfeit.

72. On March 23, 2021, Gilead, through outside counsel, wrote to Safe Chain’s counsel detailing the two new complaints. Gilead demanded that Safe Chain quarantine all Gilead product in its inventory and provide all documentation, including pedigrees, of all Gilead-branded medication it had purchased since 2020.

73. Safe Chain responded on March 26, 2021. Safe Chain refused to quarantine its Gilead product in inventory or to provide documentation for all its purchases of Gilead product. Instead, Safe Chain attempted to blame the counterfeiting on Gentek, and claimed that it had ceased all purchases from Gentek.

74. On March 29, 2021, Safe Chain wrote again to disclose that the same day it sent its previous letter, it received a report from a pharmacy customer in Washington D.C. that it had purchased two counterfeit bottles of BIKTARVY®, each with different lot numbers, from

Safe Chain. Safe Chain stated it was sending samples of those counterfeits to Gilead, and attached their pedigrees, which showed Safe Chain acquired one of the counterfeits from Boulevard.

75. The pedigrees showed that Safe Chain purchased these two counterfeits from Boulevard months *after* Gilead informed Safe Chain that Boulevard was using fake pedigrees to sell illegitimate Gilead medication and instructed Safe Chain to quarantine the medication and report it to the FDA. Instead, Safe Chain continued buying from Boulevard and subsequently sold dangerous counterfeits supplied by Boulevard to pharmacies, where they were dispensed to unsuspecting patients, placing the patients' health and lives at risk.

4. Safe Chain's Willful Sales of Counterfeits from Rapids Tex

76. As alleged above, on March 29, 2021, Safe Chain informed Gilead of two additional counterfeit reports from a pharmacy, one bottle of which Safe Chain purchased from Boulevard. Safe Chain purchased the other counterfeit from a Texas distributor, Mr. Unlimited LLC ("Mr. Unlimited") who in turn had purchased it from another Texas distributor, Rapids Tex Wholesales Corp. ("Rapids Tex").

77. Safe Chain's March 29 letter was the first time Gilead learned that Safe Chain was buying counterfeits from Mr. Unlimited and Rapids Tex. Safe Chain had sold that particular counterfeit to a Washington D.C. pharmacy on March 22, and the pharmacy reported it as counterfeit on March 26. But Safe Chain knew it was buying counterfeits from Mr. Unlimited and Rapids Tex well before that.

78. On or before March 9, 2021, Safe Chain received what it identified as counterfeit bottles of BIKTARVY® from Mr. Unlimited, which had purchased them from Rapids Tex. Safe Chain never reported those counterfeits to Gilead, nor did it quarantine them as

required by the DSCSA. Instead, Safe Chain returned the bottles to Rapids Tex for a refund. Safe Chain's co-conspirator, Defendant Brosius of Worldwide Pharma, explained in an email:

There are 3 LOTS of Biktarvy from Gilead that have proven to be bad/counterfeit. . . . our legal counsel told us we could not take/receive these lots of Biktarvy. There were 3 units on the prior invoice. Gilead and the California BOP [i.e., Board of Pharmacy] have deemed those 3 lots as 'bad.' We explained to Rapids Tex and they understood. thanks.

Rapids Tex responded by announcing "we will be shipping out today another order."

79. Receiving counterfeit Gilead medication from Rapids Tex did not deter Safe Chain and Worldwide Pharma from continuing to buy several hundred more bottles of purported Gilead medication, all with fraudulent pedigrees and at too-good-to-be true pricing, through these entities.

80. Rapids Tex's next shipments contained more counterfeit BIKTARVY® with new lot numbers – the confirmed counterfeit BIKTARVY® that Safe Chain reported to Gilead on March 29, plus two more tested and confirmed counterfeits that were reported by a different pharmacy the following month. These confirmed counterfeits are the ones that were reported to the dispensing pharmacy and to Safe Chain, and which Safe Chain chose to report to Gilead. There are almost certainly many other counterfeits that were never reported to Gilead.

5. Safe Chain Continues Its Counterfeiting, and Attempts Another Blatant Lie to Cover It Up

81. As the reports of Safe Chain's sales of counterfeits to pharmacies continued to come in, Safe Chain eventually promised Gilead that it had stopped purchasing from the counterfeit suppliers that Gilead knew about: Gentek, Boulevard, and Mr. Unlimited / Rapids Tex. But Safe Chain did not agree to stop buying and selling Gilead HIV medications

from illegitimate suppliers. Instead, Safe Chain came up with another scheme to cover its tracks and throw off Gilead’s investigation.

82. On an April 20, 2021 call between Gilead’s counsel and Safe Chain’s counsel, Safe Chain stated that it had a new source for Gilead products that was buying directly from Cesar Castillo LLC (“Cesar Castillo”), a Gilead authorized distributor. Gilead asked Safe Chain to produce pedigrees for those purchases, but Safe Chain did not do so.

83. On May 3, 2021, Gilead served subpoenas on Safe Chain, Boulevard, and Mr. Unlimited as part of an ongoing lawsuit in Florida federal court concerning fraudulent diversion of Gilead HIV medications (the “Florida Action”). The following day, Safe Chain’s counsel memorialized in a letter Safe Chain’s earlier representation that it now had a legitimate source for Gilead product:

Safe Chain has begun making purchases of Gilead-branded products from a supplier who sourced them from Cesar Castillo (Gilead’s authorized distributor). As I mentioned, **Safe Chain has contacted Cesar Castillo to verify that this supplier is not only a customer of Cesar Castillo, but also that their account number on file with Cesar Castillo matches the account number that was listed on the Cesar Castillo invoices provided by the supplier to Safe Chain substantiating the supplier’s purchase of Gilead products from Cesar Castillo.** Safe Chain is willing to provide the list of lot numbers and expiration dates for the products which Safe Chain had purchased from the supplier who sourced them from Cesar Castillo, along with the T3 reports, **provided Gilead agrees to meet the conditions below.**

(emphasis added). The “conditions” that Safe Chain demanded were untenable. They included “[w]ithdrawal of the Subpoena served on May 3, 2021,” and the following:

Please provide an **acknowledgement that Safe Chain has not falsified any of the T3 Reports** previously provided to Gilead (as had been previously insinuated) **and provide a release to Safe Chain regarding its sales of Gilead-branded medications.** . . . if [Gilead] would like Safe Chain to continue voluntarily producing additional information to Gilead, it will need this protection in place. This is perhaps the most important requirement.”

(emphasis added).

84. Gilead, of course, did not agree to falsely “acknowledge” that Safe Chain never falsified a pedigree (in fact, Safe Chain had falsified pedigrees), to withdraw the subpoena, or to give a blanket release of all its legal claims against Safe Chain. And so Safe Chain kept the identity of its new supplier secret.

85. On May 28, 2021, The Medicine Shoppe, the pharmacy customer who had received multiple counterfeits from Safe Chain, provided Gilead copies of its communications with Safe Chain, including pedigrees. Among the documents were four pedigrees for Gilead HIV medications, including BIKTARVY®, that The Medicine Shoppe received from Safe Chain on April 19, 2021. Consistent with Safe Chain’s representations to Gilead, the pedigrees did show an initial sale to Cesar Castillo, the authorized Gilead distributor. The pedigree also identified Safe Chain’s new mystery supplier: Synergy Group Wholesalers LLC (“Synergy”). The pedigrees purport to show that Synergy purchased the Gilead HIV medications from Cesar Castillo and immediately sold them to Safe Chain.

86. Gilead’s subsequent investigation revealed that those pedigrees are fraudulent, and that Safe Chain’s claim that it had verified the purchases from Cesar Castillo was a lie. Gilead never sold the lot numbers listed on the pedigrees to Cesar Castillo. Cesar Castillo has never sold Gilead products (or any other products) to Synergy, has never heard of either Synergy or Safe Chain, and was never contacted by Safe Chain. In fact, Cesar Castillo has never sold a Gilead product to another distributor, period: it sells only to pharmacies and to medical facilities like hospitals and clinics.

87. Gilead’s investigation has further revealed that Synergy is a sketchy, fly-by-night operation in the same mold as Safe Chain’s other counterfeit suppliers. Synergy

received its pharmacy distribution license in September 2020, just months before it started selling to Safe Chain. It is not licensed to sell drugs across state lines to Safe Chain's warehouses, and it is not registered with the FDA. It has no website or Internet presence.

88. The Medicine Shoppe's files included an additional pedigree concerning purchases of nearly 100 bottles of Gilead HIV medications, including BIKTARVY®, from Safe Chain in early March 2021. The pedigree states that Synergy purchased the drugs directly from Gilead. That is false. Synergy is not an authorized distributor, and it has never bought directly from Gilead.

89. Safe Chain's flagrant lies – lying about having a “new” distributor who was purchasing directly from a Gilead authorized distributor, and lying about having directly verified those purchases with the authorized distributor – were intended to stymie Gilead's investigation and to conceal Safe Chain's continued purchase and sale of dangerous counterfeit Gilead HIV medications.

E. Additional Evidence of Safe Chain's Willfulness

1. Safe Chain Purchased and Sold the Counterfeits at an Impossible Discount

90. Gilead sells to all its U.S. authorized distributors at a list price known as the wholesale acquisition cost, or WAC. But Safe Chain purchased and sold supposed Gilead medication from its counterfeit suppliers at prices well below WAC – meaning the drugs somehow got less expensive *after* Gilead sold them and they passed through various distributors' hands.

91. In fact, Safe Chain and Worldwide Pharma actively advertised to pharmacies that their sales prices were below WAC. Safe Chain and Worldwide Pharma knew that was an impossible discount for authentic, legitimately sold Gilead medication.

2. Safe Chain Purchased Gilead Medication with Obviously Fake Pedigrees

92. The pedigrees that Safe Chain received from its counterfeit suppliers were riddled with errors and anomalies, including stating the same drug was delivered to multiple recipients in different states, all on the same day; indicating that a drug was sold before the upstream distributor even received it; and leaving multiple required fields on the pedigrees blank. At minimum, these errors and inconsistencies were suspect, triggering Safe Chain’s obligation under the DSCSA to conduct an investigation. Instead, Safe Chain sold the counterfeits to pharmacies.

3. Safe Chain Knew It Was Buying from Fly-by-Night, Unlicensed, and Unauthorized Counterfeit Suppliers

93. All of Safe Chain’s known counterfeit suppliers – Gentek, Boulevard, Rapids Tex, and Synergy – are shady, fly-by-night counterfeiters who only recently opened their doors and lacked proper licensure and registration to sell prescription drugs across state lines. None of them has a website or an Internet presence. None of them are “authorized” suppliers under the DSCSA, and none of them can lawfully sell prescription medications.

94. None of the four counterfeit suppliers is registered with the FDA or has met its annual reporting requirements to the FDA. Moreover, none of them is licensed to sell pharmaceuticals in Utah or Maryland, where they shipped the counterfeit drugs to Safe Chain.

95. Checking to see whether a distributor is properly licensed and registered can be done by entering the distributor’s name into the FDA’s public online national database of pharmaceutical distributors, which takes seconds.

96. Every time Safe Chain sold a drug that it purchased from one of these counterfeit suppliers, Safe Chain affirmatively certified on its pedigree that it “received the

product from a person that is authorized as required under the Drug Supply Chain Security Act.” Every one of those certifications was knowingly false.

a. Boulevard

97. Defendant Boulevard is not licensed as a pharmaceutical distributor. Boulevard is licensed as a retail pharmacy. All of its sales of prescription drugs to an out-of-state distributor like Safe Chain are illegitimate on their face.

98. Boulevard’s owner and principal, Defendant Shukurov, owns another pharmacy that is involved in a massive prescription drug fraud scheme that is the subject of a federal prosecution, and Shukurov is an unindicted co-conspirator in that scheme.

99. After its counterfeiting came to light, Boulevard abandoned its small offices in a condominium building in Queens and stopped answering its phones.

b. Gentek

100. Gentek is run out of its principal’s home on a lot zoned for residential use in Stamford, Connecticut.

101. When a pharmacy reported to Safe Chain that it had sold the pharmacy a counterfeit bottle of Gilead HIV medication with a foreign drug inside one of its counterfeits, Defendant Charles Boyd, Safe Chain’s co-founder and CEO, emailed Gentek’s principal to ask for a refund. Charles Boyd emphasized that he was seeking a refund only for “this one bottle.” The supplier’s response email was as follows, with the all-caps and punctuation errors in the original:

GOOD MORNING
WILL CREDIT SAFE CHAIN FOR THE PRODUCT. PLEASE GO AHEAD
AND DESTROY THE PRODUCT .THATS A MIXED BATCH ERROR ON
OUR AD.

SORRY FOR ANY INCONVENIENCE.

**Edel Reyes
PESIDENT**

The abbreviation “AD” stands for “authorized distributor.” The typo “PESIDENT” appears in the signature block of every email Gentek sent to Safe Chain.

102. That was the entirety of the “explanation” Safe Chain’s supplier provided for the counterfeit Gilead HIV medication. That “explanation” was nonsensical and betrayed Gentek’s startling misunderstanding of how pharmaceutical distribution works. Gilead sells to its authorized distributors filled, sealed, ready-to-dispense bottles of Gilead medication. Authorized distributors do not open or repackage those bottles. To claim that a counterfeit bottle containing the wrong medication is the result of an authorized distributor’s “mixed batch error” is an obvious and deeply concerning misrepresentation.

103. Despite knowing that Gentek’s explanation was clearly false, Safe Chain did not object. Instead, Charles Boyd of Safe Chain wrote back cheerily to inquire about his refund: “Thanks! Please let me know how you would like to handle the credit.”

c. Rapids Tex

104. In order to facilitate its purchase of counterfeits from Rapids Tex, Safe Chain and Worldwide Pharma conspired to identify and bribe what they called a “pass-through” wholesaler: Mr. Unlimited.

105. Unlike Rapids Tex, Mr. Unlimited is an “authorized” distributor under the DSCSA: it has been licensed in Texas as a drug distributor since 2009, maintains a current registration and files annual reports with the FDA, and has an out-of-state pharmaceutical distributor’s license in Utah. Under the pass-through scam, Rapids Tex nominally sold to Mr. Unlimited, who immediately forwarded the supposed Gilead medications to Safe Chain. Rapids

Tex and Mr. Unlimited then papered the “pass-through” transaction by creating, after the fact, invoices, purchase orders, and pedigrees claiming that Mr. Unlimited purchased from Rapids Tex and sold to Safe Chain.

106. The purpose of the pass-through scam was to use Mr. Unlimited’s licensure to “whitewash” the pedigrees. It allowed Safe Chain to claim it was buying directly from a legitimate supplier (Mr. Unlimited) when in fact it was sourcing fake Gilead medications from the unlicensed, fly-by-night counterfeiter Rapid Tex. For its participation in the scheme, Mr. Unlimited was paid an up to \$1500 kickback per order. Safe Chain listed that kickback as a separate line item on its purchase orders as “PASS THROUGH FEE.”

107. Safe Chain’s upper management orchestrated the pass-through scam with Brosius and Worldwide Pharma. Safe Chain, Worldwide Pharma, Mr. Unlimited, and Rapids Tex are all on numerous emails concerning the pass-through scam. When complications arose with the scam, Mr. Unlimited told a Safe Chain employee that he “spoke with Safe Chain’s owner,” and instructed Safe Chain’s representative to get the details from Worldwide Pharma.

108. Safe Chain’s “pass through” scam had one shortcoming: the pedigrees it received from Mr. Unlimited still listed the unlicensed counterfeiter Rapids Tex as an upstream supplier. When the patient complaints continued to roll in and Gilead’s investigation intensified, Safe Chain began to create new fraudulent pedigrees that simply erased Rapids Tex from the chain of sale completely. For example, in March 2021 Safe Chain sold several dozen bottles of BIKTARVY® to The Medicine Shoppe. As with several other orders, Safe Chain had ordered those bottles directly from Rapids Tex and caused it to be “passed through” Mr. Unlimited. And yet Safe Chain’s pedigree for the sale to The Medicine Shoppe fraudulently indicated that Gilead had sold the drugs directly to Mr. Unlimited, with no mention of Rapids Tex whatsoever.

109. All of the pedigrees that Mr. Unlimited generated for Safe Chain as part of the pass-through scam stated that Mr. Unlimited received the drugs from Rapids Tex. The fraudulent pedigrees claiming that Gilead sold directly to Mr. Unlimited were created by Safe Chain itself, out of whole cloth.

F. Worldwide Pharma’s Willful Counterfeiting

110. Worldwide Pharma advertises itself as a marketing “sales engine” that connects pharmaceutical distributors with independent pharmacies. Worldwide Pharma is founded, owned, and operated by Brosius, who at all relevant times was and remains under federal indictment for health care fraud. Worldwide Pharma and Brosius conspired with Safe Chain to traffick the counterfeits. Worldwide Pharma and Brosius both worked directly with counterfeit suppliers and with unwitting customers, as well as operated behind the scenes to coordinate and assist Safe Chain in its willful purchase and sale of counterfeit Gilead HIV medications.

111. Worldwide Pharma and Brosius were copied on Safe Chain’s purchases of counterfeit Gilead HIV medications from Safe Chain’s counterfeit suppliers. Worldwide Pharma and Brosius marketed Safe Chain’s products – which, unbeknownst to the customers, were counterfeits – to pharmacies, and convinced pharmacies to buy the counterfeits from Safe Chain. Worldwide Pharma and Brosius also interfaced directly with pharmacies during the purchasing process, sending Safe Chain’s invoices and pedigrees directly to pharmacy customers, including pharmacy customers located in New York.

112. Brosius was previously the chairman of the board of an independent pharmacy, and was tasked with bringing the pharmacy into compliance with federal law and

regulations. Instead, Brosius used his position to run a vast, \$35-million health care fraud scheme through the pharmacy.

113. According to the indictment, Brosius caused his former pharmacy to send fake “test” claims to various insurers in order to pinpoint which precise ingredients in particular compounded medications would result in the largest insurance payoff for the pharmacy. Brosius then created preprinted prescription pads that listed a handful of high-value compound medications that could be prescribed by checking a box. Brosius then caused a company he owned, Pharma Sales Group, Inc. (a predecessor to Worldwide Pharma) to hire marketers to recruit physicians who used virtual or remote-consultation platforms. These physicians used Brosius’s check-box prescription pads to prescribe unnecessary medications to patients, many of whom they never examined, and then sent the prescriptions to Brosius’s pharmacy to get filled. To prevent patients from objecting or returning the medication, Brosius caused the pharmacy to waive the patients’ co-insurance, and caused money orders to be forged in the amount of the co-pays submitted to the pharmacy. Brosius caused the pharmacy to pay a percentage of the insurance reimbursements to his wholly owned company.

114. Brosius was indicted on four counts of health care fraud as well as conspiracy to commit health care fraud, and payment of kickbacks in connection with a federal health care program, and conspiracy to violate the anti-kickback statute on or about July 10, 2020.

115. Prior to the indictments, Brosius’s pharmacy hired external counsel to conduct an internal investigation, which ended with Brosius being instructed to resign from the board. Immediately after being drummed out of his pharmacy, Brosius founded Worldwide Pharma. Brosius is listed as the company’s registered agent and president on the corporate

registration, and lists the company's business purpose as "consulting services for pharmaceutical dispensing."

G. Boulevard and Shukurov's Willful Counterfeiting

116. Boulevard sold multiple confirmed counterfeits to Safe Chain, and many additional bottles of Gilead HIV medications with fraudulent pedigrees that listed initial sales from Gilead that did not occur. Boulevard of course knew that it had not purchased the counterfeits from the legitimate sources it fraudulently listed on the fake pedigrees.

117. On May 3, 2020, Gilead served Boulevard with a federal subpoena in connection with an ongoing litigation in the Southern District of Florida that involves illegally diverted bottles of Gilead HIV medications with false pedigrees, including large quantities of medication purchased back from patients. Boulevard was duly served and received the subpoena, but chose not to respond in any way.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
FEDERAL TRADEMARK INFRINGEMENT (15 U.S.C. § 1114(1)(a))

118. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

119. In violation of 15 U.S.C. § 1114(1)(a), Defendants, independently and in conspiracy with one another, used in commerce, without Gilead's consent, either a reproduction, counterfeit, copy or colorable imitation of the Gilead Marks and the Gilead Trade Dress in connection with the sale, offering for sale, distribution, or advertising of counterfeit Gilead products; in connection with the sale, offering for sale, distribution, or advertising of Gilead products with altered and/or falsified pedigrees that are materially different from authentic Gilead products authorized for sale by Gilead in the United States and that are not subject to and

subvert Gilead's quality-control measures; and in connection with which such use that is likely to cause confusion, or to cause mistake, or to deceive.

120. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.

121. Defendants are directly, contributorily, and vicariously liable for their infringement.

122. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.

123. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

124. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

SECOND CLAIM FOR RELIEF
FEDERAL TRADEMARK INFRINGEMENT (15 U.S.C. § 1114(1)(b))

125. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

126. In violation of 15 U.S.C. § 1114(1)(b), Defendants, independently and in conspiracy with one another, reproduced, counterfeited, copied, or colorably imitated the registered Gilead Marks and Trade Dress belonging to Gilead and applied such reproduction, counterfeit, copy or colorable imitation to labels, signs, prints, packages, wrappers, receptacles, or advertisements intended to be used in commerce upon or in connection with the offering for

sale, distribution or advertising of counterfeit Gilead products; in connection with the sale, offering for sale, distribution, or advertising of Gilead products with altered and/or falsified pedigrees that are materially different from authentic Gilead products authorized for sale by Gilead in the United States and that are not subject to and subvert Gilead's quality-control measures; and in connection with such use that is likely to cause confusion, to cause mistake, or to deceive.

127. For example, and without limitation, the Defendants used counterfeit, reproduced, copied, or colorably imitated Gilead Marks on the labels of the counterfeit bottles of Gilead HIV medications they purchased, advertised, and sold, as well as on altered and/or falsified pedigrees for bottles of Gilead HIV medications.

128. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.

129. Defendants are directly, contributorily, and vicariously liable for their infringement.

130. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.

131. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

132. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

THIRD CLAIM FOR RELIEF
FALSE DESCRIPTION AND DESIGNATION OF ORIGIN IN COMMERCE

133. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

134. In violation of 15 U.S.C. § 1125(a)(1)(A), Defendants, independently and in conspiracy with one another, in connection with the counterfeit Gilead medication, and in connection with Gilead products with altered and/or falsified pedigrees that are materially different from authentic Gilead products authorized for sale by Gilead in the United States, and/or that are not subject to and subvert Gilead's quality-control measures, used in commerce a slogan, trade dress, word, term, name, symbol, or device, or any combination thereof, or a false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which was or is likely to cause confusion or to cause mistake, or to deceive as to an affiliation, connection, or association with Gilead.

135. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.

136. Defendants are directly, contributorily, and vicariously liable for their infringement.

137. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.

138. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

139. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

FOURTH CLAIM FOR RELIEF
FEDERAL FALSE ADVERTISING

140. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

141. In violation of 15 U.S.C. § 1125(a)(1)(B), Defendants, independently and in conspiracy with one another, in connection with the sale of counterfeit Gilead medication, and in connection with the sale of Gilead products with altered and/or falsified pedigrees that are materially different from authentic Gilead products authorized for sale by Gilead in the United States and that are not subject to and subvert Gilead's quality-control measures, used a slogan, trade dress, word, term, name, symbol, or device, or any combination thereof, or a false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, and qualities of the counterfeit Gilead medication.

142. Defendants advertised, marketed, and promoted the counterfeit Gilead products, and the materially different Gilead products with altered and/or falsified pedigrees, to the public, and/or to specific segments of the public, using the Gilead Marks and Trade Dress, as well as other intellectual property belonging to Gilead.

143. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.

144. Defendants are directly, contributorily, and vicariously liable for their infringement.

145. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants' conduct is restrained, Gilead will continue to be irreparably harmed.

146. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

147. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

FIFTH CLAIM FOR RELIEF
FEDERAL DILUTION OF MARK

148. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

149. The Gilead Marks and Trade Dress are famous and distinctive within the meaning of 15 U.S.C. § 1125(c).

150. Defendants are selling and/or have sold counterfeit, altered, and/or falsified products bearing the Gilead Marks and Trade Dress after such trademarks and trade dress became famous.

151. By selling these products, Defendants, independently and in conspiracy with one another, have diluted and are diluting the distinctive quality of a mark or trade name owned by Gilead in violation of 15 U.S.C. § 1125(c).

152. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.

153. Defendants are directly, contributorily, and vicariously liable for their infringement.

154. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants' conduct is restrained, Gilead will continue to be irreparably harmed.

155. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

156. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

SIXTH CLAIM FOR RELIEF
NEW YORK DILUTION OF MARK AND INJURY TO BUSINESS REPUTATION

157. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

158. All of the Gilead Marks and Trade Dress are individually distinctive under New York General Business Law § 360-1.

159. By selling counterfeit, altered, and/or falsified products bearing the Gilead Marks and Trade Dress, Defendants, independently and in conspiracy with one another, have injured and are continuing to injure Gilead's business reputation and/or have diluted and are continuing to dilute the distinctive quality of a mark or trade name owned by Gilead, in violation of New York General Business Law § 360-1.

160. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in

the industry. Unless Defendants' conduct is restrained, Gilead will continue to be irreparably harmed.

161. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

162. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

SEVENTH CLAIM FOR RELIEF
NEW YORK DECEPTIVE BUSINESS PRACTICES

163. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

164. In violation of New York General Business Law § 349, Defendants, independently and in conspiracy with one another, are selling, offering for sale, and/or distributing counterfeit, altered, and/or falsified products unlawfully bearing the Gilead Marks and Trade Dress.

165. As a direct and proximate result of Defendants' deceptive conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.

166. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

EIGHTH CLAIM FOR RELIEF
COMMON-LAW UNFAIR COMPETITION

167. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

168. In violation of the common law of the State of New York and elsewhere, Defendants, independently and in conspiracy with one another, have unfairly competed with Gilead by selling the counterfeit, altered, and/or falsified products.

169. As a direct and proximate result of Defendants' unfair competition, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants' conduct is restrained, Gilead will continue to be irreparably harmed.

170. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

171. As a direct and proximate result of Defendants' unfair competition, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

NINTH CLAIM FOR RELIEF
COMMON-LAW UNJUST ENRICHMENT

172. Gilead realleges and incorporates by reference paragraphs 1 through 117 of this Complaint as if fully set forth herein.

173. By selling the counterfeit, altered, and/or falsified products bearing Gilead's valuable trademarks independently and in conspiracy with one another, Defendants have been unjustly enriched at Gilead's expense in violation of the common law of New York and elsewhere.

174. Under principles of equity, Gilead is entitled to restitution and/or disgorgement of Defendants' ill-gotten gains.

PRAYER FOR RELIEF

WHEREFORE, Gilead demands judgment against Defendants as follows:

A. preliminarily and permanently enjoining, each and every one of the Defendants and their subsidiaries, parents, affiliates, agents, servants, employees, members, directors, officers, and attorneys, and those persons in active concert or participation with them:

- (i) from selling any Gilead medication, whether genuine or counterfeit;
- (ii) from using any of the Gilead Marks and Trade Dress or any marks confusingly similar thereto in connection with the manufacture, sale, offer for sale, distribution, advertisement, or any other use of medication;
- (iii) from using any logo, trade name, or trademark confusingly similar to any of the Gilead Marks and Trade Dress, which may be calculated to falsely represent or which has the effect of falsely representing that the services or products of Defendants or of others are sponsored by, authorized by, or in any way associated with Gilead;
- (iv) from directly, contributorily, and vicariously infringing any of the Gilead Marks and Trade Dress;

- (v) from otherwise unfairly competing with Gilead in the manufacture, sale, offering for sale, distribution, advertisement, or any other use of Gilead medications;
- (vi) from falsely representing themselves as being connected with Gilead or sponsored by or associated with Gilead or engaging in any act which is likely to cause the trade, retailers, and/or members of the purchasing public to believe that Defendants, or any of them, are associated with Gilead;
- (vii) from using any reproduction, counterfeit, copy, or colorable imitation of any of the Gilead Marks and Trade Dress in connection with the publicity, promotion, sale, or advertising of medications;
- (viii) from affixing, applying, annexing or using in connection with the sale of any goods, a false description or representation including words or other symbols tending to falsely describe or represent such goods as being authentic Gilead medication and from offering such goods in commerce;
- (ix) from diluting the Gilead Marks and Trade Dress;
- (x) from destroying any records documenting the manufacture, sale, offer for sale, distribution, advertisement, or receipt of any product purporting to be Gilead medication; and

(xi) from assisting, aiding, or abetting any other person or business entity in engaging in or performing any of the activities referred to in subparagraphs (i) through (x) above; and

B. ordering that, within fifteen days after the entry and service of a preliminary or permanent injunction, Defendants serve and file a written report under oath setting forth in detail the manner and form in which they have complied with the injunction; and

C. ordering that all infringing material be turned over, seized, impounded, and/or destroyed; and

D. awarding to Gilead punitive damages from each Defendant in an amount to be ascertained at trial, but in no event less than \$25 million; and

E. awarding to Gilead statutory or actual damages in an amount to be ascertained at trial, and costs and attorney's fees; and

F. awarding to Gilead an accounting, and an award of: (i) all ill-gotten profits from Defendants' manufacture, sale, and/or distribution of the counterfeit medication; (ii) Gilead's lost profits; and (iii) Gilead's remedial costs; and

G. awarding to Gilead pre-judgment and post-judgment interest; and

H. awarding such other and further relief to Gilead as may be just, proper, and equitable.

Dated: July 22, 2021



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